

MOMETASONE FUROATE- mometasone spray, metered
Amneal Pharmaceuticals NY LLC

Mometason Furoate Nasal Spray, 50 mcg

Drug Facts

Active ingredient (in each spray)

Mometasone furoate anhydrous (glucocorticoid) 50 mcg

Purpose

Allergy symptom reliever

Uses

temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

- nasal congestion
- runny nose
- sneezing
- itchy nose

Warnings

Only for use in the nose. Do not spray into your eyes or mouth.

Do not use

- in children under 2 years of age
- to treat asthma
- if you have an injury or surgery to your nose that is not fully healed
- if you have ever had an allergic reaction to this product or any of the ingredients

Ask a doctor before use if

- have an eye infection
- have or had glaucoma or cataracts

Ask a doctor or pharmacist before use if you are taking

- medicine for HIV infection (such as ritonavir)
- a steroid medicine for asthma, allergies or skin rash
- ketoconazole pills (medicine for fungal infection)

When using this product

- the growth rate of some children may be slower
- stinging may occur for a few seconds right after use
- you may start to feel relief within 12 hours and full effect after several days of

regular, once-a-day use

- do not share this bottle with anyone else as this may spread germs
- remember to tell your doctor about all the medicines you take, including this one

Stop use and ask a doctor if

- you have, or come in contact with someone who has chicken pox, measles or tuberculosis
- your symptoms do not get better within 7 days of starting use or you get new symptoms such as severer facial pain or thick nasal discharge. You may have something more than allergies, such as an infection.
- you get a constant whistling sound from your nose. This may be a sign of damage inside your nose.
- you get an allergic reaction to this product. Seek medical help right away.
- you get new changes to your vision that develop after starting this product
- you have severe or frequent nose bleeds

Pregnancy/Breastfeeding

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- Read insert (inside package) for how to:
 - prime the bottle
 - use the spray
 - clean the nozzle
- shake well before each use
- use this product only once a day
- do not use more than directed

Adults & children 12 years of age and older

- two sprays in each nostril once daily while sniffing gently

Children 2 to 11 years of age

- The growth rate of some children may be slower while using this product. **Children should use for the shortest amount of time necessary to achieve symptom relief. Talk to your child's doctor if your child needs to use the spray for longer than two months a year.**

- an adult should supervise use
- one spray in each nostril once daily while sniffing gently

Children under 2 years of age

- **do not use**

Other information

- **do not use if sealed package is torn or opened**

- keep package and insert. They contain important information.
- store between 20° to 25°C (68° to 77°F)
- discard 75 days after first use of the product

Inactive ingredients

benzalkonium chloride, citric acid, glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, polysorbate 80, purified water, sodium citrate

Questions or Comments?

Questions or Comments?

Call 1-877-835-5472 (Mon-Fri, 9AM-5PM EST)

Distributed by:

Amneal Pharmaceuticals LLC

Bridgewater, NJ 08807

Rev. 01-2023-00

User Guide

MOMETASONE FUROATE NASAL SPRAY

24-Hour Allergy Symptom Reliever

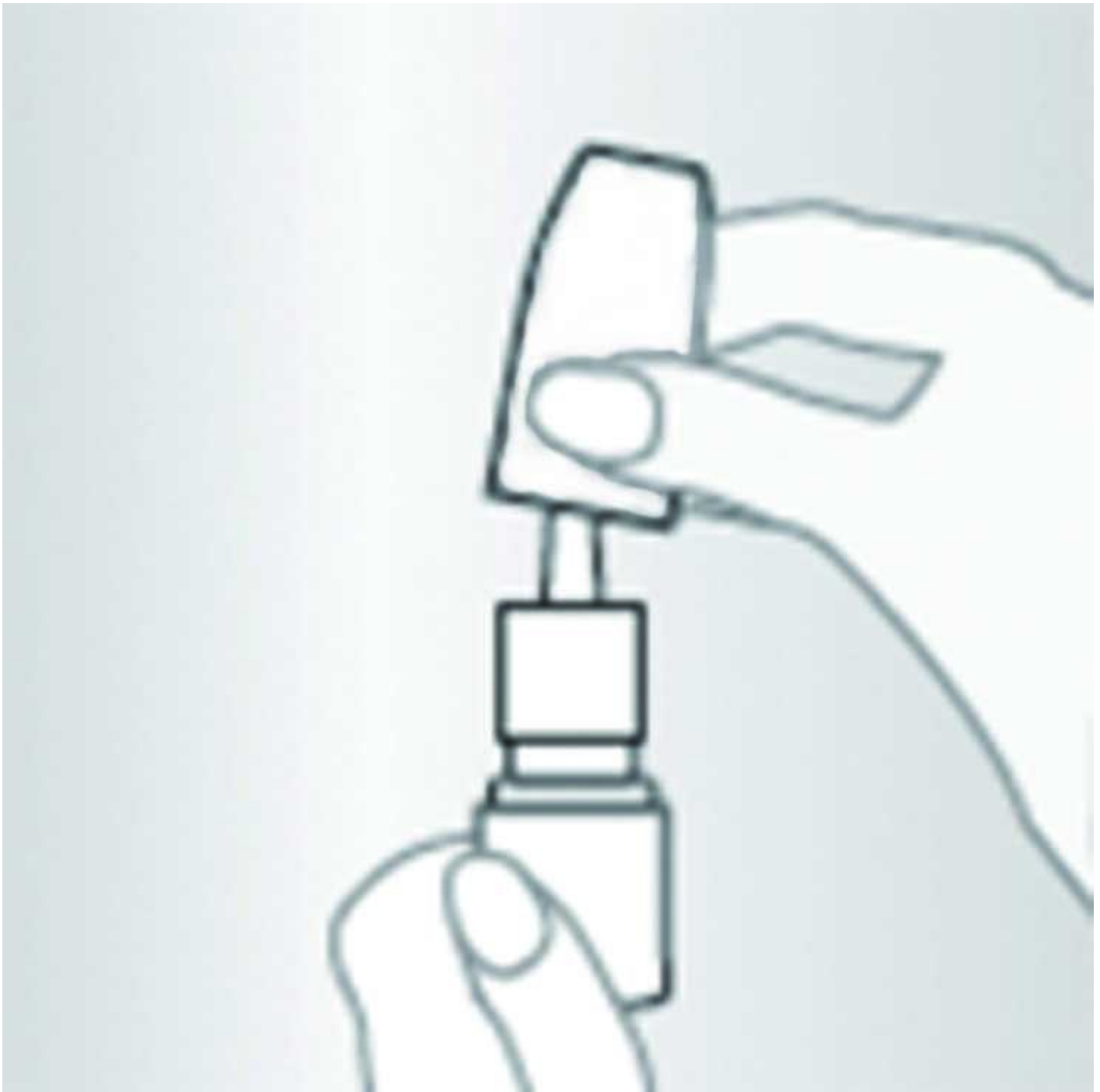
A. GETTING STARTED

Mometasone Furoate Nasal Spray 24-Hour Allergy works best at relieving your allergy symptoms when you get a full dose. Here's how to get started, in five easy steps.

1. SHAKE



Shake spray bottle well.



Remove cap.

2. PRIME

Do this when:

- Starting a new bottle
- Bottle has not been used in one week
- Just cleaned nozzle

Otherwise go to step 3



Aim away from face. Grasp spray bottle as shown. Pump until fine mist appears. Pumped ten times and still no mist? Spray nozzle may be clogged. See **KEEP IT CLEAN**, on the other side.

NOTE: There is enough medicine in the bottle to allow for priming sprays plus the number of sprays labeled on the bottle.

3. BLOW

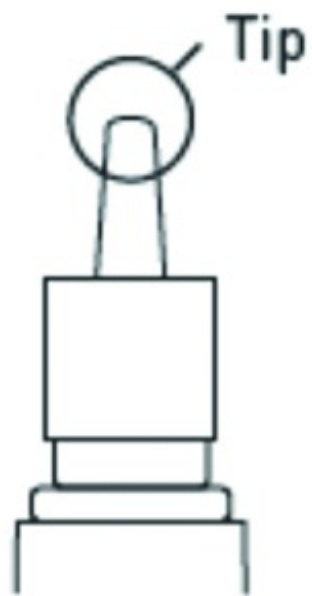


Blow nose gently to clear nostrils.

4. AIM



Close one nostril and put tip of spray nozzle in other nostril.



Put just the tip into your nose.



Aim slightly away from the center of nose.

5. BREATHE AND SPRAY



While sniffing gently, press down on spray nozzle once or twice (according to dosing instructions). You'll feel a light mist in your nose. Breathe out through your mouth.

Repeat in other nostril.

Wipe spray nozzle with clean tissue and replace cap.

Dosing and Cleaning instructions

See other side ➤

B. DIRECTIONS FOR USE

Mometasone Furoate Nasal Spray 24-Hour Allergy works best when you use

it daily. Here's how to get started.

Children age 2 to 11



An adult should supervise use

Use one spray in each nostril once daily.

Check with your child's doctor if child needs to use Mometasone Furoate Nasal Spray for longer than two months a year.

Users age 12 or older



Use two sprays in each nostril every day.



WARNING: Do not spray in your eyes. Only for use in your nose.

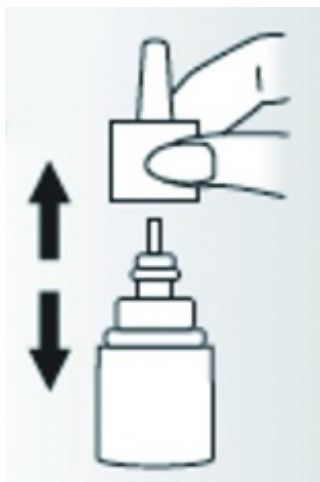
Other important information for use

- **Do not use more than directed.**
- If you forget a dose, do **not** double the next dose.
- Do not spray into eyes or mouth.
- If you get the spray in your eyes, rinse well with water.
- If allergy symptoms do not improve after one week, stop using and talk to a doctor.
- Do not share this bottle with anyone else as this may spread germs. Discard 75 days after first use of the product.

C. KEEP IT CLEAN

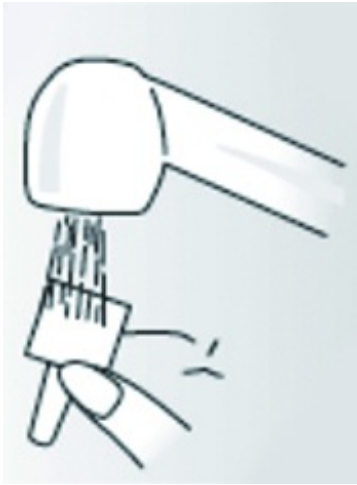
A clean spray nozzle helps ensure a full dose. Clean it weekly, or if it's clogged. Don't try to unblock nozzle with pin or sharp object - that can damage it.

1.



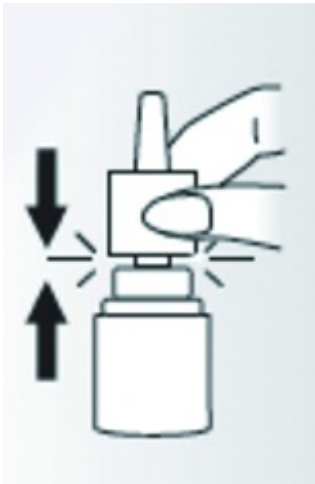
Remove spray nozzle by grasping at base and pulling up.

2.



Rinse under running tap water, and dry at room temperature.

3.



Aim away from your face and gently, but firmly, replace spray nozzle.



If spray nozzle is clogged, soak in warm water. Then repeat steps **2** and **3**.

Questions or comments? Call toll-free **1-877-835-5472**

Store between 20° to 25°C (68° to 77°F)

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Bridgewater, NJ 08807

Rev. 01-2023-00

Principal Display Panel

<p>NDC 69238-2446-2</p> <p>Mometasone Furoate Nasal Spray, 50 mcg per spray</p> <p>24 Hour Allergy Symptom Reliever (glucocorticoid)</p> <p>120 Sprays</p> <p>0.57 fl. oz. (17 mL)</p> 	<p>IMPORTANT: Read Drug Facts label and enclosed materials for important information. Children 2 to 11: 1 spray per nostril per day. Talk to a doctor if your child needs to use for longer than two months a year. Keep out of reach of children. Only for use in the nose, do not spray into the eyes. Store between 20° to 25°C (68° to 77°F). Shake well before each use.</p> <p>Questions or comments? Call toll-free 1-877-835-5472</p> <p>Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08807 Rev. 04-2022-00</p>	 <p>12.9mm x 18.63mm Non-Varnish Area</p> <p>Lot No: Exp. Date:</p>
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Drug Facts (continued)**Adults and children 12 years of age and older**

- two sprays in each nostril once daily while sniffing gently

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NDC 69238-2446-2

Mometasone Furoate Nasal Spray, 50 mcg per spray

24 Hour Allergy Symptom Reliever (glucocorticoid)***ALLERGY + CONGESTION
FULL PRESCRIPTION STRENGTH****24 Hour Relief of:**

- ✓ Nasal Congestion
- ✓ Runny Nose
- ✓ Sneezing
- ✓ Itchy Nose

Non-Drowsy / Scent-Free Mist

*Mometasone Furoate is a steroid medicine known as a glucocorticoid

**120
Sprays****0.57 fl. oz.
(17 mL)**

See below for important information about use in children.

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MOMETASONE FUROATE

mometasone spray, metered

Product Information**Product Type**

HUMAN OTC DRUG

Item Code (Source)

NDC:69238-2446

Route of Administration

NASAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MOMETASONE FUROATE (UNII: 04201GDN4R) (MOMETASONE - UNII: 8HR4QJ6DW8)	MOMETASONE FUROATE	50 ug

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
WATER (UNII: 059QF0KO0R)	

SODIUM CITRATE (UNII: 1Q73Q2JULR)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	white (white to off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69238-2446-2	1 in 1 CARTON	06/16/2023	
1		120 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207989	06/16/2023	

Labeler - Amneal Pharmaceuticals NY LLC (123797875)

Revised: 1/2023

Amneal Pharmaceuticals NY LLC